Table 1: Summary by types of incontinence*

Decision Memo for Biofeedback for Urinary Incontinence (CAG-00020N)

Decision Summary

Amend *Coverage Issues Manual 35-27* to include the following:

Biofeedback therapy is covered for the treatment of stress and/or urge incontinence in patients who failed a documented trial of pelvic muscle exercise training or who are unable to perform pelvic muscle exercises. Contractors may decide whether or not to cover biofeedback as an initial treatment modality.

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Decision Memo

To: File: Biofeedback for Treatment of Urinary Incontinence
CAG-00020N

From:

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Re: National Coverage Decision
Date: October 6, 2000

This memorandum serves four purposes: (1) outlines the description and treatment of urinary incontinence, (2) reviews Medicare's coverage history with respect to biofeedback for the treatment of urinary incontinence, (3) analyzes the relevant scientific data related to the use of biofeedback for stress, urge, and post-prostatectomy urinary incontinence, and (4) delineates the reasons for (a) supporting a positive national coverage decision for patients with stress and/or urge incontinence who have already undergone and failed a trial of pelvic muscle exercises, and (b) continues contractor discretion for the use of biofeedback as an initial treatment modality for urinary incontinence.

Pathophysiology of Urinary Incontinence

Urinary incontinence refers to the involuntary loss of urine. Approximately 17 million adults in the US suffer from incontinence, with nearly half of nursing home residents having some degree of incontinence.[1] Women are twice as affected as men. Nearly 35% of female Medicare beneficiaries and 25% of male beneficiaries are estimated to suffer from urinary incontinence.

Although the prevalence of incontinence increases with age, incontinence is not a normal consequence of aging. Incontinence can be a distressing and often disabling state in the elderly. It can have a tremendous effect on the quality of life, as well as other health conditions. Nearly a third of all patients do not speak to their doctor about incontinence, thereby increasing morbidity. [2]

Types of Incontinence

There are various types of urinary incontinence. The two most common types are stress and urge.

- *Stress incontinence* refers to involuntary loss of urine due to inadequate urethral pressure. The patients experience urine loss during coughing, sneezing, or physical exertion.
- *Urge incontinence* refers to the involuntary loss of urine due to abnormal bladder contractions (e.g. detrusor instability). It is often associated with a sudden, strong desire to urinate. The urge gives little warning and large amounts of urine are lost.
- *Mixed incontinence* is the term used when features of both stress and urge incontinence coexist.
- *Post-prostatectomy incontinence* is a common condition among elderly Medicare patients, and is a result of the treatment of prostate cancer or benign prostatic hypertrophy. [3] It is predominantly stress or urge.

There can also be functional incontinence, which occurs in a normal urinary tract. Such causes can be multifactorial and can include medications, infections, cancer, trauma, diverticuli, and fistulas.[4]

The specific diagnosis can be made by either clinical or urodynamic testing.

Treatment Options

Treatment options include behavioral modifications, medications, vaginal cones, sacral nerve stimulation, electrical and magnetic stimulation, as well as surgery. A staged approach to treatment is recommended for most patients, beginning with the most conservative techniques, progressing to more invasive treatments if initial measures are unsuccessful. The Agency for Health Care Policy and Research (AHCPR) issued the most recent guidelines for the management of urinary incontinence in 1996[5]. This decision memorandum focuses solely on the addition of biofeedback to pelvic muscle exercises.[6]

For the purposes of this decision memorandum, pelvic muscle exercises (PME) consist of planned exercising of the pelvic muscles to increase periurethral muscle strength. Biofeedback-assisted pelvic muscle exercises incorporate the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of pelvic floor muscle exercises.

Biofeedback in conjunction with PME targets skeletal muscles that are under voluntary control. Some patients have difficulty identifying, controlling, and coordinating the function of pelvic floor muscle group through verbal instructions or are uncomfortable with digital palpation. With biofeedback, these exercises are performed with simultaneous electromyographic feedback given to the patient to help facilitate awareness of the state of muscle contraction.

History of Medicare's Biofeedback Coverage Policy

Medicare's national coverage policy for biofeedback is found in Section 35-27 of the Medicare Coverage Issues Manual. It states:

"Biofeedback therapy provides visual, auditory or other evidence of the status of certain body functions so that a person can exert voluntary control over the functions, and thereby alleviate an abnormal bodily condition. Biofeedback therapy often uses electrical devices to transform bodily signals indicative of such functions as heart rate, blood pressure, skin temperature, salivation, peripheral vasomotor activity, and gross muscle tone into a tone or light, the loudness or brightness of which shows the extent of activity in the function being measured.

Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for training the pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for ordinary muscle tension states or psychosomatic conditions. (See HCFA-Pub. 14-3, §§2200ff, 2215, and 4161; HCFA-Pub. 13-3, §§3133.3, 3148, and 3149; HCFA-Pub. 10, §§242 and 242.5 for special physical therapy requirements. See also §35-20 and 65-8.)"

Medicare's biofeedback national policy does not specifically address its use for treatment of urinary incontinence. In the absence of specific national policy, Medicare contractors have the discretion to develop local medical review policies (LMRPs). Although LMRPs may vary regionally, they must include instructions limiting the service and/or identifying clinical indications for its use and determine that the service is reasonable and necessary.[7]

Contractor discretion for coverage of biofeedback began in 1991 after the March meeting of the Coverage-Payment Technical Advisory Group (TAG).[8] They discussed the use of biofeedback therapy for urinary incontinence and stated that, while there was an absence of scientific documentation of effectiveness and outcome success history, claims should not be dismissed without careful application of the "reasonable and necessary provision."

Two years later the Technical Advisory Committee (TAC), which replaced the TAG, reviewed biofeedback following the release of the Agency for Healthcare Policy and Research's (AHCPR) Clinical Practice Guideline for Urinary Incontinence. The TAC was not convinced that biofeedback made a meaningful contribution to the effectiveness of Kegel muscle exercises. It pointed out that the AHCPR report endorsed biofeedback only to the extent that it "can be useful," without specifying the degree to which or the percentage of cases in which it might be useful. They concluded "No change in policy is warranted," and coverage remained at contractor discretion.[9]

In 1997 the TAC reviewed this issue again. There was agreement that behavior therapy is the first approach to treating incontinence and that Kegel exercises "are the time-honored treatment and have an 85% effective rate." However, they found the studies on biofeedback typically were neither randomized nor controlled. They noted that the "AHCPR guidelines endorsed biofeedback as effective," but pointed out that "the guidelines do not specify whether it is superior to Kegel exercising."[10] The TAC suggested HCFA request a technology assessment on biofeedback's effectiveness for the treatment of urinary incontinence.

Later that year, the Blue Cross/Blue Shield Technology Evaluation Center (TEC) performed a technology assessment on this topic for the Office of Civilian Health and Medical Program of the Uniformed Service (OCHAMPUS/Tricare).[11] The purpose of the assessment was to "determine whether adding biofeedback to the standard behavioral treatments for urinary incontinence results in superior health outcomes, as compared to standard behavioral treatments alone." Biofeedback did not meet TEC criteria[12], and the report concluded that, "the evidence is not sufficient to demonstrate an additional benefit for biofeedback greater than that obtained with PME alone."

In early 1999, the former Director of the Coverage and Analysis Group, Grant Bagley, MD, JD, decided that biofeedback for the treatment of urinary incontinence would be presented to the Medicare Coverage Advisory Panel (MCAC), and an internal request for a national coverage decision was generated.

Technology Assessment

HCFA ordered a technology assessment from the Technology Evaluation Center (TEC) prior to the issue's referral to the MCAC. The Agency for Healthcare Research and Quality (AHRQ), formerly AHCPR, in consultation with HCFA staff, determined that TEC would be the most appropriate center to develop the evidence report. TEC had previously done an assessment on the modality and it is common practice for AHRQ to select an evidence-based practice center (EPC) that had conducted the initial assessment when a new evaluation is requested. An EPC employs rigorous, up-to-date methodology for systematically reviewing the literature on a clinical topic and forming evidence-based conclusions. By following this generally accepted methodology for performing systematic reviews, the likelihood that the conclusions are bias is minimized. A previous assessment does not predict or prejudice the outcome of a subsequent assessment. HCFA made it clear that this was to be a "de novo" assessment.

For the purpose of this assessment, the following definition of biofeedback used was "therapy that uses an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of pelvic floor muscle exercises."

To read the assessment for biofeedback seeTechnology Assessment. The results are discussed below.

The assessment addressed the following question:

For urinary incontinence patients, does adding biofeedback to PME result in greater improvement in health outcomes than the use of PME alone?

The selection criteria for the articles to be reviewed were:

- Full-length, peer-reviewed articles
- Documented stress, urge, mixed or post-prostatectomy incontinence by physician diagnosis and/or urodynamic testing
- Concurrent comparison group of patients treated with pelvic floor muscle exercises without biofeedback
- Objective measures of health outcome

- Adequate description of the patient population
- Adequate description of course and treatment delivery

A total of 8 studies comparing PME alone to biofeedback-assisted PME were included in the assessment:

- 6 trials reported on patients with stress incontinence (SI) or included a mixed population, with the majority having SI
- 1 trial compared PME alone to biofeedback plus PME in a population suffering primarily from UI
- 1 trial studied patients with post-prostatectomy incontinence

The breakdown of the studies can be seen in Table 1.

Stress Incontinence	Urge Incontinence	Post-prostatectomy Incontinence
6 studies (4 randomized) (n=321)	1 nonrandomized study (n=32)	1 randomized study (n=30)

n=number of patients
*this represents articles in the technology assessment only, and does not include articles in the exclusion tables, or articles received after the Medicare Coverage Advisory Committee (MCAC) meeting

Six articles on SI met the inclusion criteria for the TEC assessment. These studies were relatively small, with the largest including approximately 40 patients in each arm. Blinding was reported in 2 studies, and 4 studies reported some form of randomization. Overall, 3 trials reported no significant differences between groups on the outcomes of interest (Ceresoli et al. 1993, Burns et al. 1993, and Berghmans et al. 1996). Three trials (Burgio et al. 1986, Glavind et al. 1986, and Shepherd et. al. 1983) reported a greater improvement in the biofeedback-assisted PME arm over the PME alone arm, with results in 2 studies being statistically significant. In Burgio et al. patients treated with biofeedback-assisted PME reported significant improvement in incontinent episodes (76% improvement vs. 51%, $p<0.05$). Glavind et al. reported also reported positive results. Standardized pad test outcomes were assessed at the end of a 4-week trial and 3-month follow up. The biofeedback group showed a greater percentage of improvement at each interval (72% vs. -48%) and (91% vs. 22%) respectively. Shepherd et. al. showed similar results (83% improvement vs. 25% but no statistical tests of significance were reported.

Of particular note is the Burns et al. study. The mean age of the 135 female participants was 63 years (range: 57-69 years), 34% of whom were age 65 and older, making the results particularly relevant to the Medicare population. In this study, there was no significant difference in percent improvement between the biofeedback-assisted PME and PME-alone groups (61% and 54% respectively) as compared to the waiting list control subjects.

Given the mixed results of the studies reviewed in the TEC assessment, as well as various methodologic limitations, it is impossible to draw definitive conclusions on whether the addition of biofeedback to PME improves outcomes as compared to PME alone. Five of the eight studies included showed the same improvement rate for PME alone as for PME with biofeedback. The statistically significant results reported Glavind et al. could be attributed to bias. Although the trial by Glavind et al. was randomized it is subject to both performance and attrition bias. There was greater treatment intensity in the biofeedback-assisted PME group and dropouts were greater in the PME alone group. The Burgio et al. study was not randomized.

For urge incontinence, a small study (Burton et. al. 1983, n=32) was identified, of which 26% of the patients were treated for SI. As with the Burns study, the age range (64-83 years) of the participants of this study allow inferences to the Medicare population. This nonrandomized study reported statistically significant improvement in frequency of incontinence for the biofeedback-assisted PME group and the PME alone group (79% and 82% respectively). This trial does not demonstrate a significant difference in percent improvement between the biofeedback-assisted PME and PME alone groups.

For post-prostatectomy incontinence, a single trial met the selection criteria (Franke et. al. 2000). This study randomized 30 patients, mean age 61.5 years, to a biofeedback-assisted PME arm and a usual care arm. It is unclear to what extent the control group was treated with PME. This group also received educational materials and follow up that may have included biofeedback. Both groups improved significantly over time; however, there was no difference between groups in magnitude of improvement.

Assessment Conclusions

The assessment made the following conclusions:

- Evidence is not adequate to draw conclusions on whether the addition of biofeedback to PME results in improved outcomes as compared to PME alone for stress incontinence.
- Evidence suggests that there is no additional benefit to the addition of biofeedback to PME for patients with urge incontinence.
- Evidence suggests that the addition of biofeedback to PME does not result in an additional benefit for patients with post-prostatectomy incontinence.

Additional Articles Not Included as Part of the Assessment

Seven additional articles were included for the MCAC panel to review. These studies are part of the "Exclusion articles" and were not included as part of the assessment described above. Although these articles were not part of the TEC assessment, they were reviewed by HCFA staff and sent to the MCAC for consideration. These articles did not directly address the assessment question, but met some inclusion criteria and were frequently cited by advocates of biofeedback. TheExclusion Tables[PDF, 61KB] provide details of these articles.

Medicare Coverage Advisory Panel

The Medical/Surgical Procedures Panel met to discuss the topic of biofeedback for the treatment of urinary incontinence on April 12, 2000. The panel included nationally recognized experts in health services research, a urologist and former president of the American Urological Association, a urogynecologist, an obstetrics/gynecologist, and a nurse expert in incontinence. The panel was sent the technology assessment, the exclusion tables, all articles, and a catalogue of additional materials received by the agency for the panel to review. This catalogue (which included such items as the *AHCPR Guidelines on Urinary Incontinence*, position statements by specialty societies, letters by individual physicians and patients) may be found in the Catalogue of Materials [PDF, 62KB].

Thirteen people spoke during the panel meeting, representing a cross section of providers and professional societies.

Upon completion of all testimony and committee deliberations, the panel was asked to vote on two questions. If the panel vote was affirmative on the first question, they were to proceed to question number 2. If the panel voted not to affirm any part of question 1, then they would not be able to proceed to answering question 2.

1. Is the scientific evidence adequate to draw conclusions about the effectiveness of biofeedback in routine clinical use for the following three indications:1) stress incontinence, 2) urge incontinence, and 3) post-prostatectomy incontinence in the Medicare populations?

The following points were to be considered when answering this question:

Is there evidence that the studies do not over or underestimate the effect of the intervention?

- Are the results of the studies consistent or are they contradictory?
- Are the results of the studies applicable to the Medicare population?
- Do the studies permit conclusions about the effects of the technology?
- Are the results likely to apply in the general clinical setting?

2. If the evidence is adequate to draw conclusions, what is the size, if any, of the overall health effect of the addition of biofeedback to PME compared to PME alone? Please refer to the following seven categories in making this determination.

Categories of Effectiveness

Seven categories of effectiveness were presented:

- *Breakthrough technology:* The improvement in health outcomes is so large that the intervention becomes standard of care.
- *More effective:* The new intervention improves health outcomes by a significant, albeit small, margin as compared with established services or medical items.
- *As effective but with advantages:* The intervention has the same effect on health outcomes as established services or medical items but has some advantages (convenience, rapidity of effect, fewer side effects, other advantages) that some patients will prefer.
- *As effective and with no advantages:* The intervention has the same effect on health outcomes as established alternatives but with no advantages.
- *Less effective but with advantages:* Although the intervention is less effective than established alternatives (but more effective than doing nothing), it has some advantages (such as convenience, tolerability).
- *Less effective and with no advantages:* The intervention is less effective than established alternatives (but more effective than doing nothing) and has no significant advantages.
- *Not effective:* The intervention has no effect or has deleterious effects on health outcomes when compared with "doing nothing," (e.g., treatment with placebo or patient management without the use of a diagnostic test).

For question one, UI, SI, and post-prostatectomy incontinence were addressed individually. The results were:

- 8-2 that there was insufficient evidence to determine the effectiveness of biofeedback as adjunct to PME in routine clinical use in the Medicare populations for SI.
- 10-0 that there was insufficient evidence to determine the effectiveness of biofeedback as adjunct to PME in routine clinical use in the Medicare populations for UI.
- 10-0 that there was insufficient evidence to determine the effectiveness of biofeedback as adjunct to PME in routine clinical use in the Medicare populations for post-prostatectomy incontinence.

Since the panel found that there was insufficient evidence to determine the effectiveness of biofeedback, they did not proceed to the second question. However, several panel members commented that if they were to vote specifically on coverage, they would have voted yes. Some panel members noted that they felt the testimony of professional societies and experts could support a positive coverage decision.

The MCAC Executive Committee met and ratified the recommendations of the Medical/Surgical Procedures Panel on June 6. The chair of the Executive Committee submitted the decision to HCFA on July 25, 2000. Neither the Medical / Surgical panel nor the executive committee was asked to discuss the effectiveness of biofeedback when used in patients who have failed a trial of PME, or are unable to perform PME.

In the interim, HCFA continued to meet with clinical experts, professional societies, industry representatives, and other interested parties who wished to provide information to help in the decision process. The following is a brief summary of the national organizations' comments on the topic of biofeedback.

Professional Society Comments

The following represents a summary of professional societies' comments on the topic of biofeedback at the MCAC panel meeting on April 12.

The American College of Obstetricians and Gynecologists (ACOG)

ACOG states it agrees with the recommendations in the AHCPR guidelines, in general, and offer that on the basis of level-1 evidence biofeedback should be considered the standard of care for treating urinary incontinence.

American Physical Therapy Association (APTA)

Similarly, the APTA cites the AHCPR guidelines and several studies in support of biofeedback as an effective intervention for the treatment of urinary incontinence. They cite biofeedback as critical to helping patients learn to appropriately execute pelvic floor contractions.

American Urologic Association (AUA)

The AUA's position statement was based on its own literature review of the evidence by a specially formed subcommittee. Using the MCAC Executive Committee's rating system, the committee rated the evidence for biofeedback a value between level 3 (as effective with advantages) and a level 4 (as effective but with no advantages). The committee recommended further research be done such as studies to determine the ideal frequency and number of biofeedback sessions and comparison of behavioral modification with and without biofeedback.

American Urogynecologic Society (AUGS)

AUGS supports the use of biofeedback "as a technique to aid instruction and improve effectiveness for behavioral interventions, bladder training, and pelvic muscle exercises." They recommend initial diagnostic screening to ensure appropriate patient selection and defined patient selection criteria, including intact cognitive function, for patients who may be eligible to receive biofeedback.

Association for Applied Psychophysiology and Biofeedback (AAPB)

The AAPB supports the use of biofeedback in the treatment of urinary incontinence for men and women. They also note that most male incontinence is secondary to prostate surgery and may require about twice the number of therapy sessions as female patients for stress and urge incontinence. They also expressed concern that PFES and biofeedback were being viewed as "equal topics." The association pointed out that there are fundamental differences between the two, including the mechanisms of operation, clinician education and training required and relevant clinical outcomes.

Society of Urologic Nurses & Associates (SUNA) and the Wound, Ostomy, and Continence Nurses Society (WOCN) Continence Coalition

SUNA/WOCN, whose members form the Continence Coalition, advocates a "step-wise approach to control leakage and its implications." They recommend the use of biofeedback directed PME in patients with stress, urge and mixed urinary incontinence, as well as fecal incontinence and for urinary urgency and frequency for carefully selected patients, and in settings where the full range of behavioral therapies are available.

National Association for Continence (NAFC)

NAFC supports the Society of Urologic Nurses & Associates (SUNA) and the Wound, Ostomy, and Continence Nurses Society (WOCN) Continence Coalition position statement supporting coverage of biofeedback-assisted PME. Furthermore, NAFC supports the development of uniform clinical criteria which would be consistent with national policy and include access to clinical services regardless of type of residence, e.g. home health, nursing, home, assisted living, rehabilitation and outpatient settings.

HCFA Analysis

In addition to the aforementioned technology assessment, articles not included in the assessment and recommendations of the MCAC, this analysis also takes into consideration the position statements of specialty societies, and all other information received by the agency on this topic.

The majority of studies reviewed showed no benefit of biofeedback over PME alone. The studies that found no significant difference in outcomes may have lacked sufficient power to detect group differences, or biofeedback may only be effective for a subset of patients, and this benefit may not be apparent when the entire group of patients is analyzed.

The AHCPR Guideline gave a Level A Recommendation to biofeedback-assisted PME for UI, SI, and mixed incontinence. However, the guideline focused on the use of biofeedback-assisted PME compared to nothing. HCFA did not ask that question. HCFA asked: Is biofeedback plus PME more effective than PME alone (which may or may not have included non-mechanical biofeedback)? The objective was to determine how much of the benefit is due to PME alone and how much is due to the addition of biofeedback to PME. Consistent with the HCFA analysis, the AHCPR noted: "Further controlled studies are needed to demonstrate...the conditions in which biofeedback provides an added benefit to PME alone."

The MCAC was unable to draw conclusions about the effectiveness of biofeedback from the scientific evidence presented. Conversely, the general consensus of the medical professional societies, clinical experts, consumers, and others was that biofeedback adds significant benefit to patients learning to execute PMEs, and should be a covered treatment option.

Summary

The studies reviewed for biofeedback either showed conflicting results, as in the case of the six SI studies, or biofeedback was not shown to be superior to PME alone as in the case of urge incontinence and post-prostatectomy incontinence. Based strictly on the body of scientific evidence, it is not clear that biofeedback adds clinical benefit above and beyond PME alone. This contributed to the MCAC panel finding the scientific evidence presented inadequate to conclusively determine the effectiveness of the addition of biofeedback assisted PME compared to PME alone. Conversely, the professional societies' consensus statements, expert opinions, and additional analysis strongly asserted the value of biofeedback-assisted PME.

While the scientific evidence on the effectiveness of biofeedback was inconclusive, there were some studies that suggested clinical benefit from this intervention. In addition, clinical experts and professional organizations supported the use of biofeedback, based on positive clinical experience with the procedure. HCFA's conclusion based on this information is that coverage for biofeedback as initial therapy for UI should remain at the discretion of Medicare contractors. There is limited direct empirical evidence on whether biofeedback improves outcomes in patients who have failed PME or are unable to perform PME. Despite this, we felt that coverage in this situation was warranted, given the combination of suggestive scientific evidence and broad positive expert testimony. Further controlled clinical studies of this application of biofeedback would be of considerable value in clinical practice, and would confirm the appropriateness of this coverage policy.

We encourage physicians, patients, manufacturers, and others to review the recent National Coverage Determination on Clinical Trials. The decision memo details the implementation of President Clinton's Executive Memorandum on covering routine patient care costs for Medicare patients enrolled in clinical trials.[13] Such provision of Medicare funding is designed to help the Medicare program answer questions about the effectiveness of therapies on Medicare patients. It would be particularly interesting to see a clinical trial comparing the multiple behavioral therapies against each other, as well as to surgery. We would be interested in looking at this therapy again within the next three years with the hope of developing a national coverage policy for patients as an initial therapy based on high quality, rigorously designed studies.

DECISION:

Amend *Coverage Issues Manual 35-27* to include the following:

Biofeedback therapy is covered for the treatment of stress and/or urge incontinence in patients who failed a documented trial of pelvic muscle exercise training or who are unable to perform pelvic muscle exercises. Contractors may decide whether or not to cover biofeedback as an initial treatment modality.

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1 Urinary incontinence is a leading cause of admission to nursing homes.

2 In a recent study, although 75% of incontinent men expressed interest in being evaluated and treated, only 32% had brought up the problem with their primary care provider. Smoger SH, et al. *Annals of Internal Medicine* 2000;132:547-551.

3 Approximately 8% of patients who undergo transurethral resection of the prostate suffer from some degree of post-prostactectomy incontinence.

4 The classic mnemonic is DIAPPERS: delirium, infection, atrophic urethritis, pharmacologics, psychologic, endocrine, restricted mobility, stool impaction. See Resnick NM, Yalla SV. Management of urinary incontinence in the elderly. *New England Journal of Medicine* 1985;313:800-805.

5 Urinary Incontinence in Adults: Acute and Chronic Management. Clinical Practice Guideline, No. 2. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, Department of Health and Human Services, 1996 Update.

6 Decision Memorandum on Pelvic Floor Electrical Stimulation for Treatment of Urinary Incontinence (CAG-00021) can be found at http://www.cms.hhs.gov/ncdr/memo.asp?id=61.

7 Medicare Program Integrity Manual, Section 3.2

8 Coverage-Payment Technical Advisory Group Minutes, March 28, 1991, p. 4.

9 Technology Advisory Committee Minutes, February 1993, p. 7.

10 Technology Advisory Committee Minutes, May 1997, p. 20.

11 Lefevre FV. Biofeedback in the Treatment of Adult Urinary Incontinence. Chicago, IL: Blue Cross and Blue Shield Association, 1997.

12 The five criteria are (A) The technology must have final approval from the appropriate government regulatory bodies. (B) The scientific evidence must permit conclusion concerning the effect of the technology on health outcomes. (C) The technology must improve the net health outcome. (D) The technology must be as beneficial as any established alternative. (E) The improvement must be attainable outside the investigational settings.

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